In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS
No. 21-0511V

KELSEY GATES,

Petitioner,

v.

SECRETARY OF HEALTH AND HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: May 6, 2024

Paul R. Brazil, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Meghan Murphy, U.S. Department of Justice, Washington, DC, for Respondent.

RULING ON ENTITLEMENT – SPECIAL PROCESSING UNIT[1]

On January 11, 2021, Kelsey Gates filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"), alleging that she suffered a shoulder injury related to vaccine administration ("SIRVA") as a result of an influenza ("flu") vaccine administered to her on October 9, 2019. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the "SPU").

[1] Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at https://www.govinfo.gov/app/collection/uscourts/national/cofc, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the foregoing reasons, I hereby **GRANT** Petitioner's Motion for a Fact Ruling on the Record (ECF No. 27) – resolving the statutory six-month requirement, the vaccine administration site, and onset in her favor. Based on the lack of any other objections from Respondent, Petitioner has also established entitlement for a Table SIRVA Claim. The parties are urged to attempt to promptly reach an informal resolution of damages in light of the record proof of a very mild injury.

I. Procedural History

Several months after the claim's initiation and the filing of documents in its support, it was designated as an SPU matter in November 2021. I subsequently determined that several fact issues could likely be resolved while the case awaited Respondent's medical review (which at the time, was routinely taking over one year). *See* Scheduling Orders filed Dec. 17, and June 7, 2022 (ECF Nos. 17, 23).

Petitioner thereafter filed additional evidence as Exs. 8 – 10 (ECF Nos. 18, 20, 24), then her Motion for a Fact Ruling on the Record on August 9, 2022 (ECF No. 27) ("Pet. Mot."). But Respondent argued for completion of his medical review prior to any adjudication of severity. Response filed Dec. 9, 2022 (ECF No. 8) at 8; *see also id.* at 9 – 10 (disputing Petitioner's situs and onset allegations). Respondent then completed the medical review and formally opposed the claim. Rule 4(c) Report filed Mar. 31, 2023 (ECF No. 36). He also confirmed that Petitioner should file additional social media evidence. *Id.* at n. 2; followed by Pet. Exs. 11 – 12 filed on Compact Disc on Oct. 10, 2023 (ECF No. 39).

The parties subsequently agreed to pursue additional information and validation of a social media single post. Joint Status Report filed Dec. 4, 2023 (ECF Nos. 40); Order Authorizing Subpoena onto Facebook filed Dec. 6, 2023 (ECF No. 41). After the subpoena went unanswered, Petitioner's counsel obtained screenshots of the post at issue, and a statement attesting to their authenticity. Exs. 13 – 14; *see also* related Informal Communications. Petitioner, but not Respondent, took the opportunity to file supplemental briefing on the relevance of the social media posts. Pet. Supp. Memorandum filed Mar. 6, 2024 (ECF No. 44). The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a

whole. Section 13(a)(1). Petitioner's allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. *See Burns v. Sec'y of Health & Hum. Servs.,* 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. *See Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a petitioner may present testimony which is "consistent, clear, cogent, and compelling." *Sanchez v. Sec'y of Health & Hum. Servs.,* No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec'y of Health & Hum. Servs.,* No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner's injury, and the lack of other award or settlement,[3] a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

> Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the

[3] In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. *See* Section 11(c)(1)(A)(B)(D)(E).

> shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:
>
> (i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;
>
> (ii) Pain occurs within the specified time frame;
>
> (iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and
>
> (iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Evidence

I have reviewed all submitted evidence including all medical records and affidavits, as well as the Petition, the Rule 4(c) Report, and both parties' briefing. The following section focuses on the evidence most relevant to the disputed criterion.

Petitioner was born in 1991. Pre-vaccination medical records indicate that she was employed as a teacher, with two young children, and had insurance coverage through her husband's military affiliation. *See, e.g.*, Ex. 3 at 158, 228; Ex. 7 at 11. Her medical history included obesity associated with generalized joint pain, migraines, and mental health counseling. *See, e.g.*, Ex. 3 at 107-08.

Petitioner received the at-issue vaccine at a local H-E-B Pharmacy on October 9, 2019. *See* Ex. 4 at 1 (duplicated at Ex. 3 at 73); Ex. 5 at 5. The pharmacy subsequently represented that its "records do not contain… location of administration." Ex. 6 at 1 (Apr. 22, 2021, email to Petitioner's counsel).

One day later, on October 10, 2019, Petitioner posted on Facebook a photo of a bandage on her left shoulder/ upper arm, and the caption: "The smile is a lie but the bandaid is real. #vaccinated #flu season." Ex. 11 – "Posts" Folder – "Your_Posts" Subfolder.

Two months later, on December 13, 2019, in a Facebook Group entitled "Where the Science Things Are,"[4] Petitioner posted the same photo and a longer caption, stating that "I got my flu vaccine on October 9th this year and within 24 to 48 hours I started to feel pain in my shoulder (on the same side I received the vaccine). It seemed a little different from anything I had experienced before but I kind of ignored it thinking it would go away… So now it's December and my shoulder still hurts. I also have a limited range of motion…" Ex. 13 at 1.

After considering that she might need physical therapy ("PT"), Petitioner conducted internet research on what she was experiencing and discovered information about SIRVA and the Vaccine Program. Ex. 13 at 1. She resolved to seek medical attention, but she was nervous about mentioning her concerns of a vaccine injury. *Id.* After another individual mentioned the potential of a vaccine being "given too high [and…] go[ing] into the joint capsule," Petitioner wrote: "I remember thinking that it was high up on my arm." *Id.* at 7 – 8. Petitioner also wrote: "Turns out, my doctor isn't at that office anymore… So, I have to transfer my care to another PCP. Appointment isn't until January 13th but I'm on a wait list if anything comes up sooner." *Id.* at 8.

On January 13, 2020, Chaitanya Alli, M.D., took over Petitioner's primary care. *See* Ex. 3 at 52 ("transfer from Dr. Eseh-Logue" at the same practice group). Petitioner's chief complaint was left shoulder pain that was intermittent, gradually worsening, aggravated by activity and lying down, and not relieved by acetaminophen. *Id.* The injury had been present "since October 2019… no history of extremity trauma… She is not sure when she injured it… [She] thinks it started after she received her flu vaccine." *Id.* A physical exam found decreased ROM and positive impingement signs. *Id.* at 54. Dr. Alli's assessment was left rotator cuff tendinitis, for which she prescribed meloxicam (Mobic), activity restrictions, PT, and following up in 4 weeks. Ex. 3 at 55; *see also* Ex. 5 at 6 (pharmacy record of meloxicam).

Upon starting PT on January 20, 2020, Petitioner reported "L shoulder pain since Oct. 2019." Ex. 9 at 51. "[A] flu shot… inflamed her shoulder. Pain has become progressively worse… Current pain: 4/10." *Id.* A physical exam found decreased ROM

[4] "Where the Science Things Are" describes itself as a forum for members to "offer opinions, personal experiences, and discuss evidence," while cautioning that "*[n]othing* replaces an ongoing relationship and treatment from qualified medical professionals." Ex. 13 at 1 (emphasis in the original).

(164 degrees flexion; and approximately 85 degrees on abduction, and internal and external rotation), positive impingement signs, and biceps tenderness. *Id.* at 49. The therapist assessed left rotator cuff and biceps tendinopathy, to be treated with formal PT and a home exercise program ("HEP"). *Id.* at 51 – 54.

At the next formal PT session on February 4, 2020, Petitioner reported that she had been performing her HEP up to twice per day. Ex. 9 at 42. By February 21, 2020, she felt that her shoulder had improved a lot since the start of PT. *Id.* at 38. And by the fourth formal PT session on February 28, 2020, Petitioner had achieved her goals of increased ROM (170 degrees flexion and abduction) and improved function (over 60/80). *Id.* at 32. She no longer had pain or difficulty sleeping or with general movements, only with certain activities such as opening jars, lifting items to waist level or overhead, pushing up on hands, and carrying a small suitcase. *Id.* at 34. The therapist provided an updated HEP and told Petitioner to reach out if she needed additional formal therapy. *Id.* at 31-33.

There is thereafter a gap in formal treatment of any kind of slightly over five months. On August 3, 2020, Petitioner presented to a local emergency room for evaluation of acute abdominal pain. After a CT scan and abdominal and pelvic ultrasound were found to be negative, she was told to follow up with primary care within 2 – 3 days. Ex. 10 at 54 - 57. These records do not specifically document the left shoulder. *See generally* Ex. 10.

Petitioner was unable to schedule a timely appointment with Dr. Alli, and instead obtained an August 6, 2020, telemedicine encounter with a new primary care provider, Bianca Persaud, M.D. Ex. 7 at 10, 28. The encounter was again focused on the acute abdominal pain, for which Dr. Persaud prescribed simethicone. *Id.* at 28 – 30.

Petitioner missed an appointment with Dr. Alli to discuss "shoulder pain" on September 21, 2020. Ex. 3 at 46. But they met two weeks later, on October 5, 2020:

> Patient has been having shoulder pain for a long time. She thinks it has been more than a year. Denies any triggering events or falls or injuries after which it came on. She just woke up 1 day and started feeling it she thought she slept wrong, but the pain gradually continued almost on a daily basis to a point that is it limiting her range of motion significantly. She was seen here before. She was sent for physical therapy but that has to be discontinued secondary to pandemic. She denies any tingling or numbness or pain radiating into the arm. Denies any falls. May use NSAIDs as needed. Though after a few sessions of therapy initially in the beginning of year shoulder pain did improve to some extent she still has pain on a daily basis even picking up groceries or any movements involving picking up any

> weight with that arm feels pain and weakness. PT was doing PT, but stopped during COVID and now she needs a new order.

Dr. Alli's physical exam found "pain with abduction and external rotation about 90 degrees. Positive Hawkins, liftoff test, empty can test. Normal arc sign, normal internal and external rotation." *Id.* at 27. Dr. Alli assessed a left rotator cuff tendinitis, prescribed meloxicam, referred to PT, and told Petitioner to return if her symptoms worsened or failed to improve. *Id.* at 28. During the October 5, 2020, encounter, Petitioner also received a flu vaccine in her right deltoid. *Id.* at 29.

Upon restarting PT at the same practice on October 14, 2020, Petitioner reported that her left shoulder injury was causing difficulty sleeping, and increased difficulty with activities of daily living, lifting items to waist level and overhead, pushing up on hands, and carrying a small suitcase. Ex. 3 at 23 - 24. She recounted that formal therapy at the beginning of 2020 had been helpful, but had been "stopped" by the Pandemic. *Id.* at 16. She was "still better than when she initially started PT," notwithstanding the ongoing complaints. *Id.* On physical examination, her left shoulder had full ROM with pain at the end range (rated 5/10), impingement, and instability. *Id.* at 17. The therapist assessed that she had "excellent rehab potential." *Id.* Petitioner returned for formal PT on October 16, 21, 26, 28, and 30, and November 2, 2020. Ex. 9 at 7 – 12. There is no formal discharge summary. *See generally* Ex. 9.

Petitioner's left shoulder was used for administration of a Tdap vaccine, during an appointment with the primary care physician Dr. Persaud on December 9, 2020. Ex. 7 at 22 – 23. There are no further medical records.

IV. Findings of Fact

After a review of the entire record, I find that preponderant evidence supports Petitioner's entitlement for a Table SIRVA.

The first issue to be resolved is whether Petitioner has demonstrated residual effects of the alleged injury for more than six months after the October 9, 2019, vaccination. Section 11(c)(1)(D)(i). This is a threshold requirement for pursuing compensation under the Program. *Black v. Sec'y of Health & Hum. Servs.*, 33 Fed. Cl. 546, 550 (1995) (reasoning that the "potential petitioner" must not only make a *prima facie* case, but clear a jurisdictional threshold, by "submitting supporting documentation which reasonably demonstrates that a special master has jurisdiction to hear the merits of the case"), *aff'd*, 93 F.3d 781 (Fed. Cir. 1996) (internal citations omitted).

Respondent's severity objections are based on the "lengthy gap" in left shoulder treatment, including one "no-show," and two encounters for unrelated complaints (between February 28 – October 5, 2020). Rule 4(c) Report at 5 – 6. Respondent's objection is not unreasonable, particularly given that Petitioner's overall treatment was very conservative, and that she raised very minor complaints upon voluntarily discontinuing her formal PT in favor of a home exercise program, *before* the Pandemic emerged. But "a discharge from medical care does not necessarily establish that there are no residual effects." *Herren v. Sec'y of Health & Hum. Servs.*, No. 13-1000V, 2014 WL 3889070, at *3 (Fed. Cl. Spec. Mstr. July, 18, 2014), cited in Brief at 5. There is also evidence that Petitioner's PCP encountered a scheduling backlog in mid-2020,[5] and that Petitioner subsequently recounted a chronic injury with no intervening causes. Her providers also documented ongoing objective complaints, particularly of pain on the upper limits of ROM. Overall, there is preponderant evidence that Petitioner's alleged shoulder injury persisted (at a minor level) throughout the treatment gap, and therefore for over six months.[6]

Second, Respondent questions Petitioner's allegation that the subject vaccine was administered in her left, injured shoulder. Resp. Response at 7. Petitioner has not able to produce a contemporaneous record going towards that fact – but only because no such record was maintained by the pharmacy. *See* Ex. 6 at 1. And Petitioner has filed contemporaneous non-medical photographic evidence of a band-aid on her left shoulder within one day after the vaccination, Ex. 11, as well as later medical records reflecting her history of a left-sided administration, *see, e.g.*, Ex. 9 at 51.[7] In the absence of any evidence or additional persuasive argument to the contrary, Petitioner has established a likely left-sided administration.

The third disputed issue is the timing of Petitioner's shoulder pain onset. 42 C.F.R. §§ 100.3(a) and (c)(10)(ii). On this point, Respondent emphasizes the initial 96-day delay before treatment, followed by somewhat non-specific descriptions of pain starting "after" the vaccine. Response at 9 – 10; Rule 4(c) Report at 7 – 8. But Petitioner correctly notes

[5] Additionally, Petitioner's unexplained failure to attend a September 21, 2020, PCP appointment to discuss her shoulder pain is not particularly probative given that she returned to that provider just two weeks later.

[6] This severity determination is made based on a review of the medical record evidence and the parties' legal arguments. Respondent previously averred that "severity required a medical determination," *see* Response at 7 - 9. But while Respondent opposed severity in the subsequently-filed Rule 4(c) Report only reiterating Petitioner's treatment gap, and does not appear to include any particular "medical analysis."

[7] The Federal Circuit has stated that "[m]edical records, in general, warrant consideration as trustworthy evidence . . . [as they] contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions." *Cucuras*, 993 F.2d at 1528 (emphasis added).

that such specificity is not required for a legal determination in her favor, and that "no medical record or other evidence explicitly puts onset at *more* than 48 hours." Brief at 6.

Petitioner's December 2019 Facebook post helps to supplement her onset allegation. First, while Respondent objects that the evidence is "unauthenticated," Petitioner made diligent efforts to satisfy this concern – including unsuccessful service of a subpoena onto Facebook, followed by a legal assistant's sworn statement of how she screen-shotted the post. And while Petitioner's post references the Vaccine Program, it also recounts her plan to seek medical attention – and was made within a group devoted to discussing various medical/ scientific issues. While not entitled to the same weight as a medical record, it is nonetheless entitled to some weight, in assessing Petitioner's belief of when her shoulder pain began. Overall, the evidence preponderates in favor of shoulder pain beginning within 48 hours of the vaccine's administration.

Conclusion and Scheduling Order

Based on a full review of the record and the lack of any further objections from Respondent, I find that Petitioner has established entitlement to compensation for a Table SIRVA.

As the case proceeds to the damages phase, both parties shall refer to the above review of the medical records – which reflect a three-month initial treatment delay, very conservative treatment (most prominently, limited prescriptions for meloxicam; short courses of formal PT; and self-discharges to a HEP); and Petitioner's apparent acceptance of another vaccine in the subject left shoulder approximately 14 months into the course. It is also noted that Petitioner previously represented that no Medicaid lien exists in this case, and she conveyed a demand, apparently limited to past pain and suffering, for Respondent's consideration. *See* Scheduling Order filed June 7, 2022 (ECF No. 23); Pet. Status Report filed Aug. 9, 2022 (ECF No. 26). Based on these factors and the case's age, the parties shall promptly endeavor to reach an informal resolution of damages – and if that is not possible, consider requesting the case's inclusion at an upcoming Motions Day.

Accordingly, Petitioner shall file a status report updating on the progress made toward informally resolving damages by no later than Friday, June 14, 2024. The status report shall state the date by which Respondent responded to the previously-submitted demand. If Respondent has not yet responded, the parties shall confer, and Petitioner shall report the date by which Respondent expects to respond.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master